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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,609	10/09/2001	Shlomo Gabbay	SHEP5010US	8158
26294	7590	04/27/2004	EXAMINER	
TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 526 SUPERIOR AVENUE, SUITE 1111 CLEVEVLAND, OH 44114			PELLEGRINO, BRIAN E	
		ART UNIT	PAPER NUMBER	3738
DATE MAILED: 04/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/973,609	GABBAY, SHLOMO
	Examiner	Art Unit
	Brian E Pellegrino	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-28, 49-57 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-28, 49, 50, 53-57 and 60 is/are rejected.
- 7) Claim(s) 51 and 52 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50,53-57,60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 50 recites two "body portions that extend from the cylindrical member". It is unclear if there is multiple cylinders or one cylinder and this is a typographical error. Claim 60 depends from claim 50.

Claim 53 recites the limitation "the open end" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to what "open end" is being referred to. Claims 54-57 depend from claim 53.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18,19,53,54,56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. (5855601). Fig. 4 shows a heart valve prosthesis with a valve 35 mounted within a support having a plurality of support features 33 and an outer sheath 37. Bessler et al. also disclose the heart valve prosthesis is implanted using an enclosure or catheter that receives the prosthesis and is discharged by a

plunger, col. 4, lines 53-66. With respect to claim 54 the cylindrical member can have a diameter about 15mm since the stent can have this diameter, col. 6, lines 14,15. However, Bessler fails to disclose the use of a pulmonic valve. It would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Bessler such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 18 because both heart valve prostheses perform the same function of being restrained in a first condition in a delivery device and then expanded into a second condition when implanted and provides a functioning valve replacement.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Vesely et al. (5549665). Bessler is explained supra. However, Bessler fails to disclose the use of a sheath to cover the exposed parts of the support. Vesely et al. teach to cover the exposed parts of the stent support (Figs. 2,4) using a sheath or covering 35. It would have been obvious to one of ordinary skill in the art to use a sheath as taught by Vesely with the prosthesis of Bessler such that the stent support is covered to provide a smooth surface so no rigid structure can cause trauma to the surrounding tissue. Additionally, the sheath would prevent contact of the metal support with surrounding tissue and eliminate any possibility of irritation or allergic reaction to metal.

Claims 2-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Shokoohi et al. (6077296). Bessler et al. is explained supra. However, Bessler does not disclose a plurality of supports with the biasing element being in the form of a spring and a connecting element in the form of a cord to limit the outward radial expansion of the prosthesis. Shokoohi et al. teaches (Fig. 2) an expandable prosthesis with a plurality of support features **54** joined by connecting element **56**. It can also be seen at the proximal and distal ends **55,59** that the projections extend radially outward and are triangular. Shokoohi also teaches that suture can be used to limit the outward expansion, col. 7, lines 32-39. Shokoohi also shows (Fig. 11) that the support features can have springs **60** at the ends for receiving the suture so sections attached will not separate. It would have been obvious to one of ordinary skill in the art to use additional supports and flared ends as taught by Shokoohi et al. with the prosthesis system of Bessler et al. such that a larger device can be used to accommodate a larger individual or area of treatment and also provide better anchoring ability within the vessel. It would have been obvious to one of ordinary skill in the art to modify the bends (34) of Bessler and incorporate the springs of Shokoohi such that it provides better attachment structure that will not separate.

Claims 50,55,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Del Toro (5733267). Bessler et al. is explained supra. However, Bessler does not disclose a handle portion attached to the body of a cylindrical member for delivering the prosthesis. Del Toro teaches (Fig. 4) a handle **40** attached to the body of a cylindrical delivery device **32**. It would have been obvious to

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one of ordinary skill in the art to use a handle as taught by Del Toro with the delivery device of Bessler such that the surgeon can accomplish accurate control of the delivery device. With respect to claim 60, Bessler in view of Del Toro fail to disclose the use of a pulmonic valve. It would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Bessler in view of Del Toro such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 60 because both heart valve prostheses perform the same function of being restrained in a first condition in a delivery device and then expanded into a second condition when implanted and provides a functioning valve replacement.

Claims 20,21,28,49,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Torossian (5851210). Bessler et al. is explained supra. However, Bessler does not disclose the delivery device with a body portion having a greater outer diameter than the elongated cylindrical chamber that holds the prosthesis or indicia along the exterior of the cylindrical member. Torossian shows (Figs. 6A-C) a body portion **100** of the catheter having a greater diameter than the cylinder. Torossian teaches the greater diameter portion is for alignment purposes in the implantation procedure, col. 7, lines 60-63. With respect to claim 21, Bessler discloses the support structure can be made of shape memory alloy, col. 6, lines 3-5. It would have been obvious to one of ordinary skill in the art to use the greater diameter

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body portion of the catheter with the delivery device of Bessler such that it enables the surgeon to accurately place the prosthesis at the implantation site. Torossian also teaches (Fig. 2) indicia **54** are placed on the cylindrical member or catheter. Torossian additionally teaches the indicia are used to facilitate implantation of the device, col. 6, lines 26-28. It would have been obvious to one of ordinary skill in the art to use indicia on the delivery device as taught by Torossian with the system of Bessler such that accurate placement of the prosthetic device can be done by the surgeon. With respect to claim 28, Bessler in view of Torossian fail to disclose the use of a pulmonic valve. It would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Bessler in view of Torossian such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 28 because both heart valve prostheses perform the same function of being restrained in a first condition in a delivery device and then expanded into a second condition when implanted and provides a functioning valve replacement.

Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Torossian '210 as applied to claim 20 above, and further in view of Shokoohi et al. '296. Bessler as modified by Torossian is explained above. However, Bessler in view of Torossian fail to disclose the support structure including biasing elements. Shokoohi et al. is explained supra. It would have been obvious to

one of ordinary skill in the art to incorporate biasing elements as taught by Shokoohi with the prosthesis of Bessler as modified by Torossian such that it has enhanced securing means to hold a longer prosthesis together.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Torossian '210 as applied to claim 20 above, and further in view of Vesely et al. '665. Bessler as modified by Torossian is explained above. However, Bessler in view of Torossian fail to disclose the support being covered by an outer sheath. Vesely et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate an outer sheath as taught by Vesely with the prosthesis of Bessler as modified by Torossian in order to provide a smoother outer surface and enhance the ability to insert the prosthesis through tortuous vessels.

Response to Arguments

Applicant's arguments with respect to claims 18,20,50 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Bessler uses stent structure to provide structural support to the

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valvular device. One of ordinary skill in the art would look to other stent structures to find alternative expansion designs. Additionally, since the Shokoohi stent is also formed of a wire-framework, it would have been obviously a simple modification to alter the Bessler support structure in view of Shokoohi. The same argument can be used in combining Bessler with Torossian because the indicia and marking portion aid in inserting a prosthesis in the vascular system of a patient. One of ordinary skill in the art would look to delivery systems and the means to enhance the precision of implanting them in a patient such that the surgery time is reduced.

Allowable Subject Matter

Claims 51,52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 7am to 4:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738
Brian Pellegrino

